DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 13-17 and 20 is withdrawn in view of the newly discovered reference(s) to Rawles et al. (U.S. Pat. 6,890,316). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne et al. (Patent No. 4,662,355) in view of Leschinsky et al. (Patent No. 5,439,448) and further in view of Rawles et al. (Patent No. 6,890,316).

4. Pieronne et al. disclose a system and method for pump-assisted myocardial revascularization without cardiopulmonary bypass comprising: surgically attaching a first cannula to the aorta (Fig. 1, element 14; Col. 2, lines 60-62); surgically attaching a second cannula the left atrium (Fig. 1, elements 1; Col. 2, lines 41-43); interconnecting the first and second cannulae with a first atrial-arterial shunt comprising a section of tubing having first and second ends and an interior (Fig. 1, element 3; Col. 2, lines 44-46); priming the shunt to remove air (Fig. 1, elements 4, 6, and 13; Col. 2, lines 47-48 & 66; Col. 3, lines 12-17); inserting the shunt tubing into a first peristaltic pump (Fig. 1, elements 7 & 8); and activating the pump to pump blood through the shunt and in

parallel with the patient's heart pumping action (Col. 1, lines 6-11; Col. 7, lines 52-58). Regarding first and second cannula adapters, each with a vent for priming, see the Pieronne et al. Fig. 1 on the Office Action mailed 4/24/06 where examiner marked the structure considered to meet these claim requirements. Here, examiner considers that the Pieronne et al. "air purges" (i.e. vents for priming purposes) inherently include a sealing means for selectively opening and closing the vents. Without such sealing means, the vents would create deleterious open holes in the blood circuit.

5. Pieronne et al. do not explicitly disclose that the section of tubing is translucent. Leschinsky et al. disclose a method and apparatus for interconnecting blood-carrying tubing, cannulae, and/or external pumps and provide a teaching that blood-carrying tubing is most preferably formed of a clear material (Col. 6, lines 5-7). It would have been obvious to one of ordinary skill in the art at the time of applicant's invention from the teaching by Leschinsky et al. to modify the tubing of Pieronne et al. to be translucent to provide the predictable results of enabling the clinician to view the interior of the tubing to detect bubbles or other contaminants (Col. 6, lines 5-9).

6. In addition, Pieronne et al. do not explicitly disclose a cap removably attached to each vent. The system and method of Leschinsky et al. further includes vents for removing air from the a blood-carrying circuit, wherein the vents include removably attached caps for selectively opening and closing the vents during priming (Fig. 5, elements 28 & 32; Figs. 8, 9, & 10, elements 128 & 132; Col. 7, lines 39-55; Col. 9, lines 16-57). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Leschinsky et al. to modify the priming vents

of Pieronne et al. to include removably attached caps to provide the predictable results of an easy, well-known means for closing the vents during normal pumping and for opening them during priming to allow air bubbles to escape to the external environment.

7. Regarding the limitation of Claim 13 that the "first peristaltic pump is one of a medical facility's existing peristaltic pumps from a cardiopulmonary bypass machine," the pump of Pieronne et al. is disclosed as the type conventionally used for extra-corporeal circulation and thus Examiner considers such the disclosed pump to be a medical facility's existing pump (Col. 2, lines 50-54).

8. In addition, with respect to the limitation of claim 13 that the method steps perform pump-assisted myocardial revascularization without cardiopulmonary bypass, Pieronne is directed to pump regulation circuits, including pumps utilized in a left or right side assistance system (see, for example, col. 1, lines 9-43). Examiner considers such a left or right assistance system to be performing myocardial revascularization (see col. 1, lines 19-22) without cardiopulmonary bypass (the system is used assist the heart rather than bypass the heart, and patients utilizing the assistance system can be weaned off the device as the myocardium recovers; see col. 1, lines 26-43).

9. Further, with respect to the limitation of claim 13, that the priming is done with the patients own blood to remove air, Pieronne et al. in view of Leschinsky discloses priming vents but does not state that the shunt is primed with the patients own blood. However, Rawles et al disloses using a patients blood to prime the tubes in order to prime the system without having to use a priming solution that increases the circulatory volume (Col. 9, lines 5-15). Therefore It would have been obvious to one having

ordinary skill in the art at the time the invention was made to have modified the system of Pieronne in view of Leschinsky with priming a system with the patients own blood in order to provide the predictable result of reducing the effects of using a priming solution that increases the circulatory volume.

10. Regarding Claim 14, it is inherent from Pieronne et al.'s description of the vents (Fig. 1, elements 4 & 13) as "air purges" that the vents are opened at appropriate times to allow the passing flow of blood to force out (i.e. purge) any trapped air.

11. Claims 15, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over (Pieronne et al. in view of Leschinsky et al. in view of Rawles hereinafter "Modified Pieronne") and further in view of Aboul-Hosn et al. (Patent No. 6,935.344).

12. As related above with respect to claim 13, Modified Pieronne disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Modified Pieronne do not explicitly disclose that the pump is placed within one meter of the patient or that the tubing is no longer than two meters. Aboul-Hosn et al. disclose systems and methods for left and right side heart assistance including the use of shunt tubing and peristaltic pumps (Fig. 5; Col. 18, lines 41-54). Additionally, Aboul-Hosn et al. teach that it is important to bring the pump as close to the patient as possible and to minimize priming volume, the volume of the support system that is external to the patient (Col. 5, lines 2-16; Col. 17, lines 15-26). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Aboul-Hosn et al. to modify the heart support system of Modified Pieronne to include placement of the pump within one meter of the patient and to utilize tubing

that is no longer than two meters to provide the predictable results of well-known advantages of minimizing the distance and time that blood travels outside the body, such as preventing the occurrence of hemolysis and eliminating the necessity of cooling or warming the blood (Col. 17, lines 24-39).

13. In addition, with respect to the limitation of claim 20 that the method steps perform pump-assisted myocardial revascularization without cardiopulmonary bypass, Pieronne is directed to pump regulation circuits, including pumps utilized in a left or right side assistance system (see, for example, col. 1, lines 9-43). Examiner considers such a left or right assistance system to be performing myocardial revascularization (see col. 1, lines 19-22) without cardiopulmonary bypass (the system is used assist the heart rather than bypass the heart, and patients utilizing the assistance system can be weaned off the device as the myocardium recovers; see col. 1, lines 26-43).

14. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over (Pieronne et al. in view of Leschinsky et al. in view of Rawles hereinafter "Modified Pieronne") as applied to claim 13 above, and further in view of Runge (Patent No. 5,743,845).

15. As related above, Modified Pieronne disclose a method for left side assistance including the use of a first atrial-arterial shunt and peristaltic pump. Modified Pieronne further disclose simultaneous right side assistance that utilizes right side cannulation sites and a second atrial-arterial shunt and peristaltic pump (Fig. 1, elements 4a, 7a, 8a, 13a, & 16-18; Col. 2, lines 66-68; Col. 3, lines 1-11). Modified Pieronne disclose that the

third cannula is surgically attached to the pulmonary artery, but do not explicitly disclose that the fourth cannula is attached to the right atrium. Instead the fourth cannula is described as attached to "the outlet of the organ, such as the vena cava." Runge discloses a system and method for left and right side heart support that omits the need for an oxygenator of a conventional cardiopulmonary bypass system (Figs. 4 & 5; Col. 3, lines 24-27). Runge further provides a teaching that the cannulation sites most preferred by surgeons "will be from the right atrium to the pulmonary artery, and from the left atrium to the aorta" (Col. 3, lines 9-11). It would have been obvious to one of ordinary skill in the art at the time of Applicant's invention from the teachings by Runge to modify the heart support system of Modified Pieronne to include attaching the fourth cannula to the right atrium to provide the predictable results of a cannulation configuration most preferred by surgeons.

16. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieronne etal. in view of Leschinsky et al. in view of Rawles and Runge as applied to Claim 16 above, and further in view of Aboul-Hosn et al.

17. Comments made above in rejection of Claims 3, 15, and 20 regarding tubing length and placement of the pump within one meter of the patient apply here as well.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to REX HOLMES whose telephone number is (571)272-8827. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/George R Evanisko/
Primary Examiner, Art Unit 3762

/R. H./
Examiner, Art Unit 3762